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JFCT-1-03 (CIP.1)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S):		Vilas M. Chopdekar et al.	:
			: Examiner: Shahnam J. Sharareh
SERIAL NO.	:	10/734,460	: Art Unit 1617
			: Before the Director
FILED	:	December 12, 2003	:
			:
FOR	:	OPIOD TANNATE COMPOSITIONS	

PETITION TO MAKE SPECIAL UNDER 37 CFR 1.102(d)

Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

The undersigned attorney of record, on behalf of the applicants and the assignee, hereby petitions the Director to advance the examination of this application pursuant to the provisions of 37 CFR 1. 102(d). Enclosed is a copy of Form PTO/SB/17p (11-05) and a check in the amount of $130.00 for the requisite petition fee.

This application is currently before Examiner Shahnam J. Sharareh awaiting examination. In a telephone discussion with Mr. Sharareh on February 9, 2006, the Examiner indicated that he would not reach this application for examination for at least six (6) more months, most likely in about nine (9) months.

This Petition is based on two grounds: Manufacturing and Infringement.

I. Manufacturing

(A) The assignee of this patent application, i.e., Jame Fine Chemicals, Inc., presently has sufficient capital (approximately at least one million dollars) and facilities (e.g., mixing, freeze-drying, milling, powder and packaging equipment) to manufacture the invention in quantity. Furthermore, the assignee has been certified by the FDA as having Good Manufacturing Practices. In addition, since the starting materials for the compositions of the present invention, i.e., opioids, are controlled substances, the assignee has a DEA-approved storage vault and a category 2 substance registration;

(B) The assignee will not manufacture the invention unless the patent will be granted;

(C) The assignee hereby obligates itself to manufacture the invention in the United States in a quantity immediately upon allowance of the claims or issuance of a patent which will protect the investment of capital and facilities; and

(D) The assignee has caused the undersigned attorney to carry out a careful and thorough search of the prior art. Copies of each of the references deemed most closely related to the subject matter encompassed by the claims are already of record, having been furnished with the Information Disclosure Statement and the Supplemental Information Disclosure Statement of record.

II. Infringement

(A) One of the preferred opioid tannate compositions disclosed and claimed in the instant pat application is **hydrocodone tannate**. The aforesaid **hydrocodone tannate** is currently being marketed by Hawthorn Pharmaceuticals, Inc. ("Hawthorn") of a suspension branded as "DYTAN-HC" Suspension. As may be seen from the enclosed photocopy of Hawthorn's product literature, DYTAN-HC Suspension is a grape-flavored, sugar-free, alcohol-free suspension for oral administration and each 5 ml (teaspoonful) contains:

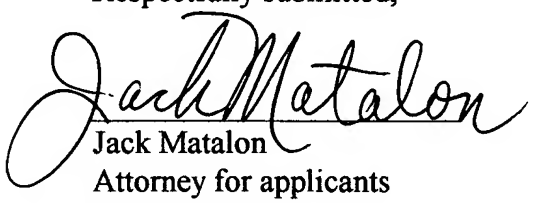
Hydrocodone Tannate .....3.5 mg
Phenylephrine Tannate .....7.5 mg
Diphenhydramine Tannate .....25 mg

(B) A rigid comparison of the DYTAN-HC Suspension marketed by Hawthorn with the claims of the instant application has been been made and, in the opinion of the undersigned attorney, some of the claims of the instant application are unquestionably infringed; and

C) That the undersigned attorney has carried out a careful and thorough search of the prior art. Copies of each of the references deemed most closely related to the subject matter encompassed by the claims are already of record, having been furnished with the Information Disclosure Statement and the Supplemental Information Disclosure Statement of record.

Based on the facts and considerations set forth above and the enclosure hereto, it is clear that the applicants are entitled to have the examination of their patent application advanced pursuant to the provisions of 37 CFR 1.1.02(d) as supplemented by Section 708.02 of the MPEP. Accordingly, it is respectfully requested that this Petition be expeditiously reviewed and granted.

Respectfully submitted,



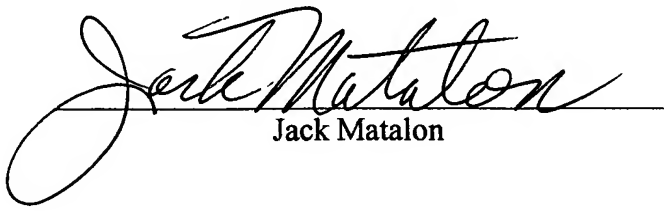
Jack Matalon
Attorney for applicants
Reg. No. 22,441

32 Shelley Rd.
Springfield, NJ 07081-2529

Tel: (973) 467-5626
Fax: (973) 921-0817

CERTIFICATE OF MAILING UNDER 37 CFR § 1.8

I hereby certify that this correspondence is being sent by first class mail to Mail Stop Petitions, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on February 10, 2006.



Jack Matalon

PTO/SB/17p (11-05)
Approved for use through 07/31/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PETITION FEE
Under 37 CFR 1.17(f), (g) & (h)
TRANSMITTAL
(Fees are subject to annual revision)

Send completed form to: Commissioner for Patents
P.O. Box 1450, Alexandria, VA 22313-1450

Application Number	10/734,460
Filing Date	Dec.12, 2003
First Named Inventor	Vilas M. Chopdekar
Art Unit	1617
Examiner Name	Shahnam J. Sharareh
Attorney Docket Number	JFCT-1-03 (CIP)

Enclosed is a petition filed under 37 CFR 1.102(d) **that requires a processing fee (37 CFR 1.17(f), (g), or (h)). Payment of $** 130.00 **is enclosed.**

This form should be included with the above-mentioned petition and faxed or mailed to the Office using the appropriate Mail Stop (e.g., Mail Stop Petition), if applicable. *For transmittal of processing fees under 37 CFR 1.17(i), see form PTO/SB/17i.*

Payment of Fees (small entity amounts are NOT available for the petition fees)

☐ The Commissioner is hereby authorized to charge the following fees to Deposit Account No._____:
☐ petition fee under 37 CFR 1.17(f), (g) or (h) ☐ any deficiency of fees and credit of any overpayments
Enclose a duplicative copy of this form for fee processing.

☒ Check in the amount of $130.00 is enclosed.

☐ Payment by credit card (Form PTO-2038 or equivalent enclosed). Do not provide credit card information on this form.

Petition Fees under 37 CFR 1.17(f): Fee $400 Fee Code 1462
For petitions filed under:
§ 1.36(a) - for revocation of a power of attorney by fewer than all applicants
§ 1.53(e) - to accord a filing date.
§ 1.57(a) - to accord a filing date.
§ 1.182 - for decision on a question not specifically provided for.
§ 1.183 - to suspend the rules.
§ 1.378(e) - for reconsideration of decision on petition refusing to accept delayed payment of maintenance fee in an expired patent.
§ 1.741(b) - to accord a filing date to an application under § 1.740 for extension of a patent term.

Petition Fees under 37 CFR 1.17(g): Fee $200 Fee Code 1463
For petitions filed under:
§ 1.12 - for access to an assignment record.
§ 1.14 - for access to an application.
§ 1.47 - for filing by other than all the inventors or a person not the inventor.
§ 1.59 - for expungement of information.
§ 1.103(a) - to suspend action in an application.
§ 1.136(b) - for review of a request for extension of time when the provisions of section 1.136(a) are not available.
§ 1.295 - for review of refusal to publish a statutory invention registration.
§ 1.296 - to withdraw a request for publication of a statutory invention registration filed on or after the date the notice of intent to publish issued.
§ 1.377 - for review of decision refusing to accept and record payment of a maintenance fee filed prior to expiration of a patent.
§ 1.550(c) - for patent owner requests for extension of time in ex parte reexamination proceedings.
§ 1.956 - for patent owner requests for extension of time in inter partes reexamination proceedings.
§ 5.12 - for expedited handling of a foreign filing license.
§ 5.15 - for changing the scope of a license.
§ 5.25 - for retroactive license.

Petition Fees under 37 CFR 1.17(h): Fee $130 Fee Code 1464
For petitions filed under:
§ 1.19(g) - to request documents in a form other than that provided in this part.
§ 1.84 - for accepting color drawings or photographs.
§ 1.91 - for entry of a model or exhibit.
§ 1.102(d) - to make an application special.
§ 1.138(c) - to expressly abandon an application to avoid publication.
§ 1.313 - to withdraw an application from issue.
§ 1.314 - to defer issuance of a patent.

Jack Matalon
Signature

Feb. 10, 2006
Date

Jack Matalon
Typed or printed name

22,441
Registration No., if applicable

CONTACT I

Mailing Address:
Post Office Box 2248
Madison, MS 39130

Physical/Shipping Address:
135 Industrial Blvd
Madison, MS 39110

Phone: (888) 455-5253
Fax: (601) 853-1567
Email:
For questions about products: info@hawthornrx.com
For questions about career opportunities: jobs@hawthornrx.com

DYTAN-HC Suspension

DESCRIPTION:
A purple, grape-flavored, sugar-free, alcohol-free suspension for oral administration.
Each 5 mL (teaspoonful) contains:
Hydrocodone Tannate ..... 3.5 mg
Phenylephrine Tannate ..... 7.5 mg
Diphenhydramine Tannate. ..... 25 mg
Inactive Ingredients: Potassium Sorbate, Methylparaben, Propylparaben, Propylene Glycol, Glycerin, Potassium Citrate, Citric Acid, Aspartame, Grape Flavor, Xanthan Gum, Lavender Color and Purified Water.
Hydrocodone Tannate is an opioid analgesic and antitussive and occurs as fine, white crystals or as a crystalline powder. It is affected by light. The chemical name is: 4,5a-epoxy-3-methoxy-17-methyl-morphinan-6-one tartrate (1:1) hydrate (2:5).
Phenylephrine Tannate is a mydriatic and a decongestant and occurs as bitter crystals. The chemical name is: (-)-m-hydroxy-a-[(methyl amino) methyl] benzyl alcohol.
Diphenhydramine tannate is an antihistaminic. The chemical name is 2-(diphenylmethoxy)-N, N-dimethylethylamine.

CLINICAL PHARMACOLOGY: **Hydrocodone Tannate:**
Hydrocodone is a semisynthetic narcotic analgesic and antitussive with multiple actions qualitatively similar to those of codeine. Most of these involve the central nervous system and smooth muscle. The precise mechanism of action of hydrocodone and other opiates is not known, although it is believed to relate to the existence of opiate receptors in the central nervous system. In addition to analgesia, narcotics may produce drowsiness, changes in mood and mental clouding. Radioimmunoassay techniques have recently been developed for the analysis of hydrocodone in human plasma. After a 10 mg oral dose of hydrocodone bitartrate, a mean peak serum drug level of 23.6 ng/mL and an elimination half-life of 3.8 hours were found.
Phenylephrine Tannate: Phenylephrine acts predominantly by a direct action on alpha (a) adrenergic receptors. In therapeutic doses, the drug has no significant stimulant effect on the beta (b) adrenergic receptors of the heart. Following oral administration, constriction of blood vessels in the nasal mucosa may relieve nasal congestion. In therapeutic doses the drug causes little, if any central nervous system stimulation.
Diphenhydramine Tannate: Diphenhydramine Tannate is an ethanolamine antihistamine with anticholinegric (drying) and sedative effects. It competitively antagonizes histamine at H1 histamine receptors in the central nervous system and in the periphery. Histaminergic effects (increased capillary permeability and dilatation, edema formation, "flare" and "itch" response, vasoconstriction and vasodilatation, and gastrointestinal and smooth-muscle constriction) are specifically blocked by diphenhydramine. H1 antihistamines competitively antagonize histamine binding and do not block its release.

INDICATIONS:
DYTAN-HC is indicated for the symptomatic relief of cough, nasal and eustachian tube congestion and discomfort associated with the common cold, sinusitis and acute upper respiratory tract infections.

CONTRAINDICATIONS:
Hypersensitivity to hydrocodone, codeine, sympathomimetic amines, diphenhydramine, or other antihistamines of similar chemical structure. Because of its drying effect on lower respiratory secretions, DYTAN-HC is not recommended in the treatment of bronchial asthma. Also contraindicated in patients with severe hypertension or severe coronary artery disease, in patients on MAO inhibitor therapy, in patients with narrow-angle glaucoma, urinary retention, or peptic ulcer, during an asthmatic attack, in nursing mothers, and in premature or newborn infants.

WARNINGS:
Sympathomimetic amines should be used judiciously and sparingly in patients with hypertension, diabetes mellitus, ischemic heart disease, increased intraocular pressure, hyperthyroidism or prostatic hypertrophy. Sympathomimetics may produce central nervous system stimulation with convulsions or cardiovascular collapse with accompanying hypotension. Antihistamines may impair mental and physical abilities required for the performance of potentially hazardous tasks, such as driving a vehicle or operating machinery. Diphenhydramine-containing products should not be used in combination with other diphenhydramine formulations; in rare cases toxic psychosis has occurred in children who received combinations of two or more diphenydramine formulations by any route of administration including topically applied preparations.
Respiratory Depression: At high doses or in sensitive patients, hydrocodone may produce dose-related respiratory depression by acting directly on the brain stem respiratory center. Hydrocodone also affects the center that controls respiratory rhythm, and may produce irregular and periodic breathing.
Head Injury and Increased Intracranial Pressure: The respiratory depressant effects of narcotics and their capacity to elevate cerebrospinal fluid pressure may be markedly exaggerated in the presence of head injury, other intracranial lesions or a preexisting increase in intracranial pressure. Furthermore, narcotics produce adverse reactions which may obscure the clinical course of patients with head injuries.
Acute Abdominal Condition: The administration of narcotics may obscure the diagnosis or clinical course of patients with acute abdominal conditions.
Infants and Children: Diphenhydramine should not be administered to premature or full-term neonates. Infants may have greater susceptibility than adults to the toxic effects of diphenhydramine. Adults who administer diphenhydramine to children should be aware that children may be at increased risk for central nervous system stimulation. Antihistamines may impair mental alertness in children.

PRECAUTIONS:
Special Risk Patients: As with any narcotic analgesic agent, DYTAN-HC should be used with caution in elderly or debilitated patients and those with severe impairment of hepatic or renal function, hypothyroidism, Addison's disease, prostatic hypertrophy or urethral stricture. The usual precautions should be observed and the possibility of respiratory depression should be kept in mind.

Use diphenhydramine tannate with precaution in patients with narrow-angle glaucoma, stenosing peptic ulcer disease, pyloroduodenal obstruction, symptomatic prostatic hypertrophy, or bladder-neck obstruction, history of bronchial asthma, increased intraocular pressure, hyperthyroidism, cardiovascular disease, or hypertension. Elderly are more susceptible to the side effects of diphenhydramine.
Concomitant use of CNS depressants, including alcohol, may potentiate the sedative effects of diphenhydramine.

Information for Patients: DYTAN-HC, like all narcotics and antihistamines, may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery; patients should be cautioned accordingly. Antihistamines may cause drowsiness and ambulatory patients who operate machinery or motor vehicles should be cautioned accordingly.
Cough Reflex: Hydrocodone suppresses the cough reflex; as with all narcotics, caution should be exercised when DYTAN-HC is used postoperatively and in patients with pulmonary disease.
Drug Interactions: Patients receiving other narcotic analgesics, antipsychotics, antianxiety agents, or other CNS depressants (including alcohol) concomitantly with DYTAN-HC may exhibit an additive CNS depression. When combined therapy is contemplated, the dose of one or both agents should be reduced.
The use of MAO inhibitors or tricyclic antidepressants with hydrocodone preparations may increase the effect of either the antidepressant or hydrocodone. The concurrent use of anticholinergics with hyrocodone may produce paralytic ileus.
Concomitant use of antihistamines with alcohol, tricyclic antidepressants, barbiturates and other CNS depressants may have an additive effect.
MAO inhibitors and beta-adrenergic blockers increase the effect of sympathomimetics. Sympathomimetics may reduce the antihypertensive effects of methyldopa, mecamylamine, reserpine and veratrum alkaloids.
Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term studies in animals to determine mutagenic and carcinogenic potential have not been performed.
Usage in Pregnancy: *Teratogenic Effects: Pregnancy Category C.* Animal reproduction studies have not been conducted with DYTAN-HC. It is also not known whether DYTAN-HC can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity.
DYTAN-HC should be given to a pregnant woman only if clearly needed. Hydrocodone has been shown to be teratogenic in hamsters when given in doses 700 times the human dose. There are no adequate and well-controlled studies in pregnant women. DYTAN-HC should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
Nonteratogenic Effects: Babies born to mothers who have been taking opioids regularly prior to delivery will be physically dependent. The withdrawal signs include irritability and excessive crying, tremors, hyperactive reflexes, increased respiratory rate, increased stools, sneezing, yawning, vomiting and fever. The intensity of the syndrome does not always correlate with the duration of maternal opioid use or dose. There is no consensus on the best method of managing withdrawal. Chlorpromazine 0.7 to 1 mg/kg q6h, and paregoric 2 to 4 drops/kg q4h, have been used to treat withdrawal symptoms in infants. The duration of therapy is 4 to 28 days, with the dosage decreased as tolerated.
Labor and Delivery: As with all narcotics, administration of DYTAN-HC to the mother shortly before delivery may result in some degree of respiratory depression in the newborn especially if higher doses are used.
Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from DYTAN-HC, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.
Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS:
Hydrocodone Tannate: The most frequently observed adverse reactions include lightheadedness, dizziness, drowsiness, sedation, nausea and vomiting. These effects seem to be more prominent in ambulatory than in nonambulatory patients and some of these adverse reactions may be alleviated if the patient lies down.
Sympathomimetic Amines: Hyperreactive individuals may display ephedrine-like reactions such as tachycardia, palpitations, headache, dizziness, or nausea.
Sympathomimetics have been associated with certain untoward reactions including restlessness, tremor, weakness, pallor, respiratory difficulty, dysuria, insomnia, hallucinations, convulsions, CNS depression, arrhythmias and cardiovascular collapse with hypotension.
Antihistamine: Patients sensitive to antihistamines may experience mild sedation. Possible side effects of antihistamines are drowsiness, restlessness, dizziness, weakness, dry mouth, anorexia, nausea, vomiting, headache, nervousness, blurring of vision, polyuria, heartburn, dysuria and, very rarely, dermatitis.
Other adverse reactions include:
Central Nervous System: Drowsiness, mental clouding, lethargy, impairment of mental and physical performance, anxiety, fear, dysphoria, psychic dependence, mood changes.
Gastrointestinal System: The antiemetic phenothiazines are useful in suppressing the nausea and vomiting which may occur(see above); however, some phenothiazine derivatives seem to be antianalgesic and to increase the amount of narcotic required to produce pain relief, while other phenothiazines reduce the amount of narcotic required to produce a given level of analgesia.
Genitourinary System: Ureteral spasm, spasm of vesical sphincters and urinary retention have been reported.
Respiratory Depression: Hydrocodone Tannate may produce dose-related respiratory depression by acting directly on the brain stem respiratory center. Hydrocodone also affects the center that controls respiratory rhythm, and may produce irregular and periodic breathing. If significant respiratory depression occurs, it may be antagonized by the use of naloxone hydrochloride. Apply other supportive measures when indicated.

DRUG ABUSE AND DEPENDENCE:
DYTAN-HC is subject to the Federal Controlled Substance Act (Schedule III). Hydrocodone can produce drug dependence of

the morphine type and, therefore, has the potential for being abused. Psychic dependence, physical dependence and tolerance may develop upon repeated administration of DYTAN-HC, and it should be prescribed and administered with the same degree of caution appropriate to the use of other narcotic drugs.

OVERDOSAGE:
Hydrocodone Tannate: Signs and Symptoms: Serious overdose with hydrocodone is characterized by respiratory depression (a decrease in respiratory rate and/or tidal volume, Cheyne-Stokes respiration, cyanosis), extreme somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, and sometimes bradycardia and hypotension. In severe overdosage, apnea, circulatory collapse, cardiac arrest and death may occur.
Treatment: Primary attention should be given to the reestablishment of adequate respiratory exchange through provision of a patent airway and the institution of assisted or controlled ventilation. The narcotic antagonist naloxone is a specific antidote against respiratory depression, which may result from overdosage or unusual sensitivity to narcotics, including hydrocodone.Therefore, an appropriate dose of naloxone hydrochloride (see package insert) should be administered, preferably by the intravenous route, and simultaneously with efforts at respiratory resuscitation. Since the duration of action of hydrocodone may exceed that of the antagonist, the patient should be kept under continued surveillance and repeated doses of the antagonist should be administered as needed to maintain adequate respiration. An antagonist should not be administered in the absence of clinically significant respiratory or cardiovascular depression. Oxygen, intravenous fluids, vasopressors and other supportive measures should be employed as indicated. Gastric emptying may be useful in removing unabsorbed drug.
Diphenhydramine Tannate: Mild overdose of diphenhydramine leads to sedation. Moderate to severe diphenydramine overdose produces predictable anticholinergic effects: agitated delirium, mydriasis, dry mouth, decreased gastrointestinal motility, urinary retention, and erythema. Rarely, diphenhydramine overdose may cause rhabdomyolysis. Life-threatening overdose is characterized by hyperthermia (from a combination of musculoskeletal action in an agitated patient who is unable to lose heat because of an inability to sweat), seizures and ventricular tachycardia. Mild to moderate overdoses can be treated supportively. Sedation for severe agitation can be accomplished by intravenous benzodiazepines or physostigmine. Ventricular arrhythmia is treated with intravenous sodium bicarbonate or hypertonic saline.

WARNING: Phenylketonuric. Contains Phenylalanine.

DOSAGE AND ADMINISTRATION:
Adults and children 12 years of age and over: 1 to 2 teaspoonfuls (5 to 10 mL) every 12 hours; Children 6 to under 12 years of age: 1/2 to 1 teaspoonful (2.5 to 5 mL) every 12 hours; Children under 6 years of age: Consult a physician.

HOW SUPPLIED:

DYTAN-HC is a purple, sugar free, alcohol free, grape-flavored suspension available in bottles of 4 fl oz (118 mL) with NDC 63717-710-04.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN. IN CASE OF ACCIDENTAL OVERDOSE, SEEK PROFESSIONAL ASSISTANCE OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

Store at controlled room temperature, 15°- 30°C (59°-86°F). Dispense in a tight, light-resistant container as defined in the USP/NF with a child-resistant closure.

Rx Only

Manufactured for: Hawthorn Pharmaceuticals, Inc.,
Madison, MS 39110

DHCFC 10/05